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ATTORNEY DOCKET NO.	CONFIRMATION NO.
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7590 02/09/2004

ROBERT D. BUYAN  
STOUT, BXA, BUYAN & MULLINS, LLP  
SUITE 300  
IRVINE, CA 92618

EXAMINER

TELLER, ROY R

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/890,721	POMFRETT ET AL.
Examiner	Art Unit	
Roy Teller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 20 November 2003.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) 7-13, 20 and 21 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-6 and 14-19 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 011802.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

**DETAILED ACTION**

This office action is in response to the election, received 11/20/03, in which applicant elected group I, claims 1-6 and 14-19, without traverse.

Claims 1-6 and 14-19 are pending.

***Information Disclosure Statement***

The information disclosure statement, received 1/18/02, is acknowledged. A signed copy is included hereto.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-6 and 14-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 5-6, and 14-19 recite a delta-sleep inducing peptide or biologically active fragments and derivatives thereof, this is vague and indefinite for failing to specify the metes and bounds of the biologically active fragments and derivatives.

Claim 4 recites the compound in conjunction with another anesthetic agent, this is vague and indefinite for failing to identify the other anesthetic agent.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for reasons set forth above.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 14-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Schoenberger, USPN 4,165,312.

The instant invention is drawn to a use of delta-sleep inducing peptide for the manufacture of a medicament for regulating, promoting or inducing anesthesia; and for promoting or inducing sedation.

Schoenberger teaches a nonapeptide, formula 1, which has a 100% query match with the delta-sleep inducing peptide of the instant invention, see abstract. Schoenberger discloses the compound is useful in pharmaceutical compositions as sleep inducing agents, see abstract. Therefore, the reference is deemed to anticipate the instant claims above.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 and 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schoenberger, USPN 4,165,312.

The reference is relied upon for the reasons discussed *supra*.

Based upon the beneficial overall teachings provided by Schoenberger with respect to a use of the delta-sleep inducing peptide, if not expressly taught, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to adjust particular conventional working conditions therein (e.g., the use of delta-sleep inducing peptide or biologically active fragments and derivatives for the manufacture of a medicament for regulating, promoting or inducing anesthesia; and for promoting or inducing sedation)- i.e., the adjustment of particular conventional working conditions is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teaching of the reference, it is apparent that one of ordinary skill in the art would have had reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the

invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

***Conclusion***

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (571) 272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571)272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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1654  
2/3/04  
RT



CHRISTOPHER R. TATE  
PRIMARY EXAMINER

Form PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 078986-0205	SERIAL NO. 09/890,721
<b>SUPPLEMENTAL INFORMATION DISCLOSURE CITATION</b> <i>(Use several sheets if necessary)</i>		APPLICANT Pomfrett, Christopher John Douglas	
		FILING DATE August 1, 2001	GROUP ART UNIT Unassigned

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
RT	A1	4,165,312	08-21-1979	Schoenenberger	260	112.5 R	06-26-1978
+	A2	4,444,758	04-24-1984	Scherschlicht et al.	424	177	05-17-1982

**FOREIGN PATENT DOCUMENTS**

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION	
							YES	NO
RT	A3	2 000 511 A	01-10-1979	Great Britain		02	x	
+	A4	0 513 702 A2	11-19-92	Europe			x	
+	A5	0 513 702 A3	11-19-92	Europe			x	

**OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)**

RT	A6	Article titled, <u>The Phosphorylated Analogue of DSIP Enhances Slow Wave Sleep And Paradoxical Sleep In Unrestrained Rats</u> ; Mayumi Kimura, et al.; Psychopharmacology (1989) Vol. 97 pp. 35-39
	A7	Article titled, <u>DSIP Occurs In Free Form In Mammalian Plasma, Human CSF and Urine</u> ; Markus V. Graf, et al.; Pharmacology Biochemistry & Behavior, 1984 Vol. 21 pp. 761-766
	A8	Article titled, <u>Delta Sleep-Inducing Peptide-Like Material In Rat Brain As Determined By Enzyme Immunoassay: Effect Of Sleep Deprivation</u> ; Shigeru Nagaki, et al.; Neuroscience Letters, (1984) Vol. 51 pp. 253-257
	A9	Abstract No. 199699009270; Eksperimental 'naya I Klin Farmakologiya, 1996, 59 (1) pp. 8-10
	A10	Abstract No. 199698652104; Fiziologicheskii Zhurnal Imeni I M Sechenova, 1995, 81 (2) pp. 1-6
	A11	Abstract No. 199396115975; Fiziologicheskii Zhurnal (Kiev), 1992, 38 (4) pp. 27-32
	A12	Abstract No. 000088122948; Patologicheskaya Fiziologiya I Eksperimental 'naya Terapiya, 1989, 0 (2) pp. 45-49
	A13	Abstract No. 000087001742; Kardiologiya, 1988, 28 (3) pp. 89-81
	A14	Abstract No. 000081036248; Kardiologiya, 1985, 25 (5) pp. 84-88
	A15	Abstract No. 199294101504; Fiziologicheskii Zhurnal Imeni I M Sechenova, 1991, 77 pp. 1-13
	A16	Abstract No. 1998-465470

EXAMINER	DATE CONSIDERED
R. Telle	2/2/04

\* EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include any copy of this form with next communication to applicant.

<b>Notice of References Cited</b>		Application/Control No.	Applicant(s)/Patent Under Reexamination	
		09/890,721	POMFRETT ET AL.	
Examiner		Art Unit		Page 1 of 1
Roy Teller		1654		

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-4,165,312	08-1979	Schoenenberger, Guido A.	530/328
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.